

## **REMARKS**

The Office Action dated July 9, 2009, has been received and carefully noted. The above amendments and the following remarks are being submitted as a full and complete response thereto.

Claim 11 is rejected, and claims 1 and 5-21 have been objected to. Claims 1, 11, and 12 have been amended herein. Thus, claims 1 and 5-21 are pending in this application. Support for the amendments may be found in the specification as originally filed. Applicants submit that no new matter is added. Applicants respectfully request reconsideration and withdrawal of the outstanding rejections.

### ***Claim Objections***

Claims 1 and 5-21 were objected to for failing to comply with the Sequence Rules, because claims 1, 11, and 12 recited a sequence that is identified as "SEQ ID No. 1" in the claims, but the sequence does not correspond to the sequence given in the Sequence Listing. Applicants submit that claims 1, 11, and 12 have been amended to correct this error, and accordingly, Applicants respectfully request withdrawal of the objection to claims 1 and 5-21.

### ***Rejections under 35 U.S.C. §103***

Claim 11 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Danik et al. (*PNAS*, vol. 88, pp. 8577-8581 (1991), hereinafter "Danik") in view of Kapron et al. (*Protein Science*, vol. 6, pp. 2120-2133 (1997), hereinafter "Kapron") and Maloy and Cotigan ("Selection of Immunogenic Peptides for Antisera Production,"

Current Protocols in Immunology, pp. 9.3.1-9.3.5 (1991), hereinafter "Maloy").

Applicants respectfully traverse this rejection.

The Office Action indicates that claim 11 is drawn in part to an immunogenic epitope comprising SEQ ID No. 4. The Office Action notes that claim 11 does not require SEQ ID No. 4 to be glycosylated.

Danik is cited for disclosing that human gliomas express high levels of mRNA related to rat testicular sulfated glycoprotein 2, which is also known as clusterin. Danik does not teach an immunogenic epitope of clusterin that comprises SEQ ID No. 4.

Karpon is relied upon for teaching the sequence of clusterin alpha and beta (see page 2127).

Maloy is cited for disclosing the selection of a peptide from the C-terminus of a protein as an immunogen (see page 9.3.2, under the heading "Selection of a C-Terminal Peptide"). Maloy discloses that a peptide having a length of about 15 residues can be used to make an antisera that will react with the native protein (see page 9.3.3, under the heading "Selection of the Length of the Peptide").

The Office Action takes the position that it would have been *prima facie* obvious at the time the claimed invention was made to take the last 20 amino acid residues from the clusterin beta chain. One of skill in the art allegedly would have been motivated to do so by the teachings of Maloy regarding the ability of a peptide with as many as 35 residues to elicit antisera which binds to the native protein. Further, one of skill in the art would allegedly have been motivated to make a binding agent that binds to native clusterin because Danik teaches the over expression of the mRNA encoding clusterin in

human gliomas. Finally, the Office Action concludes that “[o]ne of skill in the art would want to know if the corresponding protein is also over expressed.”

Applicants respectfully disagree with the positions taken in the Office Action.

Applicants submit that the prior Declaration under 37 C.F.R. § 1.132 of Luigi G. Spagnoli demonstrated that the presently-claimed epitopes provide surprisingly strong sensitivity for detecting clusterin isoforms, and permit evaluation of clusterin increases in early stage cancer patients with higher sensitivity.

In view of the unexpected results demonstrated by the experimental data submitted in the Declaration, Applicants submit that it would not have been obvious for one skilled in the art to modify the teachings of Danik, Kapron, and Maloy to arrive at the presently claimed invention.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. § 103(a) over Danik in view of Kapron and Maloy.

### **CONCLUSION**

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event that this paper is not being timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account Number 01-2300, referencing Docket Number 026073-00007.

Respectfully submitted,



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